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Food and Drug Administration
Office of Nutritional Products, Labeling & Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740

NOV - 4 2005

October 28, 2005

RE: Dietary Supplement Claims Notification

Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that the following product is manufactured, packed and/or distributed by Hillestad Pharmaceuticals at 178 US Highway 51N, Woodruff, WI 54568.

This notification is being provided pursuant to 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a).

Product Name: **PapayaZymes**

The following statement(s) are or may be used on the labels or in the labeling of the product:

*"PapayaZymes are made from a fruit base of freeze-dried papaya, pineapple fruit powders and natural fruit sugars and contain enzymes, which aid in protein digestion."
"Papayazymes contain a blend of natural enzymes, which aid the body in digesting proteins, fats, and carbohydrates."*

I certify that the information in this notice is complete and accurate and that Hillestad Pharmaceuticals has substantiation that the statements are truthful and not misleading.

Sincerely,



Dr. Marco Sedelis
Vice President

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HOME OFFICE:

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